EU Accession - Preparing for Day 1

Organised by the
DIA Advisory Council of Europe

Zagreb, Croatia
30 November 2010

Free Workshop!

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TUESDAY | 30 NOVEMBER 2010

13:30 **Welcome Address DIA**
Dr. Brigitte Franke-Bray FFPM, Specialist in Pharmaceutical Medicine FMH, Director DIA Europe, Switzerland

Welcome Address Croatian Agency
Working within the EU regulator's Network - Future Vision
Prof. Siniša Tomić, Head of Agency, Agency for Medicinal Products and Medical Devices, Croatia

13:50 **Session 1**

Preparing for European Marketing Authorisation
Session Chairperson:
Prof. Siniša Tomić, Head of Agency, Agency for Medicinal Products and Medical Devices, Croatia

Accession Tools & EU Requirements for CP Products What Does the EMA Expect from New Member States?
Anthony Humphreys, Head of Regulatory, Procedural and Committee Support, European Medicines Agency, European Union

Regulators Assisting Regulators through Close Collaboration and Twinning Projects
Dr. Peter Bachmann, European Drug and International Affairs, BfArM, Germany, (CMD(h) Member)

What Did We Learn from Previous Accessions?
Anu Tummavuori-Liemann, Associate Director European Regulatory Liaison, Celgene, Switzerland

15:00 **Coffee Break**

15:30 **Session 2**

Facilitating Smooth Transition into the New Era
Session Chairperson:
Ivana Ferber, Regulatory Lead Croatia / Bosnia and Herzegovina, Merck Sharp and Dohme d.o.o., CARPC Member, Croatia

How Did Candidate Agencies Smoothly Transition into the EU Regulators Network?- Practical Experiences from EU Accession
Dr. Dagmar Stara, Teacher at Faculty of Pharmacy, Comenius University, Bratislava , former Head of the EU Affairs Coordination Unit at State Institute for Drug Control, Bratislava, Slovak Republic

What Are the Current Challenges and Expectations Industry Is Facing?
Ivana Ferber, Regulatory Lead Croatia / Bosnia and Herzegovina, Merck Sharp and Dohme d.o.o., CARPC Member, Croatia
Local Generic Industry association representative invited

Co-ordination of MR and DC Procedures
Christer Backman, EU Coordinator & Senior Expert, Medical Products Agency (MPA), Sweden

17:00 **End of Workshop**

For more information on this workshop or the registration, please contact us by email: Sarah.Schuppener@diaeurope.org or call: +41 61 225 51 51